UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/622,272	07/17/2003	Shanta M. Modak	070050.2429	4202

21003 7590 07/02/2009

BAKER BOTTS L.L.P.
30 ROCKEFELLER PLAZA
44TH FLOOR
NEW YORK, NY 10112-4498

EXAMINER	
ANDERSON, JAMES D	

ART UNIT	PAPER NUMBER
1614	

NOTIFICATION DATE	DELIVERY MODE
07/02/2009	ELECTRONIC

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

DLNYDOCKET@BAKERBOTTS.COM

Office Action Summary	Application No.	Applicant(s)	
	10/622,272	MODAK ET AL.	
	Examiner	Art Unit	
	JAMES D. ANDERSON	1614	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *22 April 2009*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-9,11-13,15,17 and 31-34* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-9, 11-13, 15, 17, and 31-34* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Claims 1-9, 11-13, 15, 17, and 31-34 are presented for examination

Applicants' response and amendments to the claims, filed 4/22/2009, are acknowledged and entered. No claims have been amended. Claims 33-34 are newly added. Claims 1-9, 11-13, 15, 17, and 31-34 are pending and under examination.

Response to Arguments

Applicants' arguments have been fully and carefully considered. Rejections and/or objections not reiterated from previous office actions are hereby withdrawn. The following rejections and/or objections are either reiterated or newly applied. They constitute the complete set presently being applied to the instant application.

Declaration under Rule 1.132

The Examiner acknowledges receipt of the Rule 1.132 Declaration of Gonzalo Merino ("Merino" Declaration) and has carefully considered the information provided therein. The previous rejection of claims 1-9, 11-13, 15, 17, and 31-32 under 35 U.S.C. 103 as being obvious over Modak (US 2003/0152644 A1) and Modak (USP No. 5,985,918) in view of Wei (U.S. 2002/0098159 A1) is **withdrawn** as Modak (US 2003/0152644 A1) is disqualified as applicable prior art under 35 U.S.C. 103(c) in light of the Merino Declaration.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any

evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claims 1-9, 11-13, 15, 17, and 31-34 are rejected under 35 U.S.C. 103(a) as being unpatentable over **Modak *et al.*** (U.S. Patent No. 5,985,918; Issued Nov. 16, 1999) and **Modak *et al.*** (U.S. Patent No. 5,965,610; Issued Oct. 12, 1999; Filed Jun. 9, 1997) in view of **Wei *et al.*** (U.S. 2002/0098159 A1; Published Jul. 25, 2002; Filed May 18, 2001), for the reasons of record set forth at pages 3-6 of the previous Office Action dated 1/22/2009, of which said reasons are herein incorporated by reference.

Applicant traverses the instant rejection, stating that the claims "as amended" are not obvious over the cited references when considered separately or in combination. Applicant submits that new claims 33 and 34 are not obvious over the cited references because the combined teachings of the cited prior art do not disclose all the elements of the claimed invention, namely the cited references do not teach or suggest an anti-irritant composition that does not contain zinc salicylate. Further, Applicants submit that the claims of the instant application are not obvious over the cited references because practicing the claimed invention produces surprising and unexpected results.

Applicant's traversal has been fully and carefully considered, but fails to be persuasive.

Firstly, the previously rejected claims, claims 1-9, 11-13, 15, 17, and 31-32, have not been amended as asserted by Applicants. As such, Applicant's argument that the claims "as amended" are not obvious over the cited prior art is unimpressive. With regard to newly added claims 33 and 34, while the cited prior art exemplifies compositions comprising zinc salicylate as preferred embodiments, the prior art teachings are not limited to such preferred embodiments. Note that Table A of the Modak ('918 patent) discloses a combination of 2.5% zinc stearate + 1% zinc acetate, which combination was effective in reducing itching when compared to a placebo cream not containing zinc salts (*i.e.*, itching after 1 hour compared to itching and redness after 15 minutes).

Secondly, the assertion that practice of the claimed invention produces surprising and unexpected results is not persuasive. Applicants argue that the reduction in irritation achieved by

using low concentrations of water-soluble organic zinc salts in an anti-irritant composition, as recited by the pending claims, would not have been predicted by an artisan of ordinary skill in view of the cited prior art. Applicants argue that dermal irritation *can be caused by* many different ingredients used in compositions designed for topical irritation and that topical compositions *may cause* irritation due to ingredients such as spermicides, microbicides, or alcohol-based gels. However, what *can* or *may* occur does not render the claimed compositions non-obvious over the cited prior art. Applicants have presented no factual evidence that the broadly claimed compositions comprising two or more water-soluble organic salts of zinc present at concentrations of 0.1 to 2% (weight/weight), an antimicrobial compound at a concentration of between 0.05% and 4% (weight/weight), 0.05% to 4% (weight/weight) incroquat, farnesnol, and further comprising water, ethanol, and one or more agents selected from the group consisting of a gelling agent, a thickening agent, a hydrophilic or hydrophobic polymer, an emulsifying agent, and an emollient are less irritant than compositions comprising only one organic salt of zinc, comprising higher concentrations of two or more organic salts of zinc, comprising higher concentrations of an antimicrobial compound, and/or comprising higher concentrations of incroquat.

Example 1 in the specification discloses a working example purported to demonstrate the "anti-irritant" effect of compositions according to the invention. This example provides an "anti-irritant" score based on the degree of colororation of the skin by externally-applied chlorophyllin dye subsequent to application of a gel composition of the invention. This example is unimpressive for several reasons. Firstly, it is not seen by the Examiner how inhibition of chlorophyllin dye penetration by zinc salts is a demonstration of an "anti-irritant" effect. Secondly, the combinations of two or more organic zinc salts were not significantly better than only one applied organic zinc salt. Thirdly, the results of two or more organic salts of zinc are limited to specific salt combinations in specific amounts (i.e., 3 out of 4 compositions contained 1.0% zinc gluconate and all compositions contained zinc acetate in concentrations of 0.2%, 0.4%, or 0.6%). Lastly, the combination contained no antimicrobial compounds, no incroquat, and no farnesol as required in the claimed compositions. As such, the combinations of Example 1 are not commensurate in scope with the claims.

Example 2 in the specification discloses the anti-irritant effects of compositions comprising two or more organic salts of zinc in reducing the irritating effect of methyl salicylate. While the combinations did reduce skin redness, as with Example 1 the results of two or more organic salts of zinc are limited to specific salt combinations in specific amounts (i.e., 6 out of 8 compositions contained zinc gluconate and all compositions contained zinc acetate in concentrations of 0.1%, 0.2%, 0.3%, or 0.4%). Further, the combinations did not contain antimicrobial compounds, incroquat, and farnesol as required in the claimed compositions. As such, the combinations of Example 2 are also not commensurate in scope with the claims.

Example 3 in the specification discloses the anti-irritant effects of a composition comprising 0.3% zinc gluconate, 0.1% zinc lactate, and 0.1% zinc acetate in reducing the irritating effect of nonoxynol-9. While the combination did reduce the irritating effect of nonoxynol-9, as with Examples 1 and 2 the combination did not contain antimicrobial compounds, incroquat, and farnesol as required in the claimed compositions. As such, the combinations of Example 3 are also not commensurate in scope with the claims.

Example 7 in the specification discloses the effect of a specific composition on reducing the irritating effects of latex on a volunteer. The compositions disclosed in Example 7 contained no farnesol as required by the instant claims and further are composed of specific zinc salt combination and specific excipients in very specific amounts. As such, the combinations of Example 7 are also not commensurate in scope with the claims.

Lastly, with regard to the asserted surprising and unexpected anti-irritant effects of the claimed compositions, Applicants provide no example demonstrating that the claimed concentration of between 0.1% and 2% (weight/weight) of two or more organic salts of zinc are unexpectedly superior to higher concentrations at reducing irritation. Furthermore, as acknowledged by Applicants and discussed in the previous Office Action, Modak and the '610 patent disclose that zinc salts may be incorporated into compositions at concentrations of between 1-15% or 1-10%, respectively, for reducing irritation. As such, it is not surprising or unexpected that Applicant's compositions reduce irritation because this is precisely what the prior art teaches compositions comprising zinc salts are intended to do.

Thirdly, Applicants argue that Modak suggests that high zinc salt concentrations are necessary to reduce irritation, citing the examples of Modak wherein zinc salt concentrations

above 2% were necessary for reducing latex induced irritation. However, Modak clearly and unequivocally suggests concentrations of between 1-15% or 1-10% for reducing irritation and may contain one or more other organic salts of zinc as recited in the instant claims. Thus, finding the optimal working range within the prior art disclosure is not demonstrative of an unexpected result as asserted by Applicants.

Fourthly, Applicants argue that the claims include ingredients such as an antimicrobial compound, farnesol, and ethanol, all of which *can cause* irritation when applied topically. However, as discussed supra, what can or may occur is not pertinent to the present rejection, especially in view of the cited prior art which suggests the use of organic salts of zinc to reduce skin irritation. Furthermore, as previously discussed, Applicant's tested compositions also did not contain farnesol. Applicants point to Example 13 as demonstrating the irritation reducing effects of the claimed composition in compositions comprising farnesol. However, Example 13 provides no such demonstration. Rather, the example merely provides a composition comprising farnesol but this composition was not tested for its anti-irritating effects.

Fifthly and lastly, Applicants argue that the nonobviousness of the claims is further evidenced by the surprising and unexpected synergistic antimicrobial effect achieved by combining the elements recited in the claims. Applicants point to Example 10 as demonstrating the claimed synergistic effect. The compositions of Example are outside the scope of the claimed invention. Note that Gel #6 contains three organic salts of zinc, but the concentration of zinc lactate is 0.05% which is outside the claimed range of between 0.1% to 2%. Furthermore, the compositions do not contain farnesol as required by the claimed compositions.

For these reasons *supra*, and those previously made of record at pages 3-6 of the previous Office Action dated 1/22/2009, rejection of claims 1-9, 11-13, 15, 17, and 31-34 is proper.

Conclusion

Rejection of claims 1-9, 11-13, 15, 17, and 31-34 is proper.

No claims of the present application are allowed.

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to JAMES D. ANDERSON whose telephone number is (571)272-9038. The examiner can normally be reached on MON-FRI 9:00 am - 5:00 pm EST.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Ardin Marschel can be reached on 571-272-0718. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/James D Anderson/
Examiner, Art Unit 1614

/Ardin Marschel/
Supervisory Patent Examiner, Art Unit 1614